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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,545	02/12/2004	Kristian DiMatteo	10123/04501	5754
7590 01/12/2007 Patrick Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/777,545

Applicant(s)

DIMATTEO ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-28 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 22 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 16-21, 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Newly submitted claims 25-28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: in the previous election of species made by Mr. Patrick Fay on 4/18/2006, Mr. Fay elected Species B, which is Fig. 7. Claims 25-28, however, are directed to other species, not Species B. Claims 25 and 26, for example, are directed towards Fig. 8. The claim language in claims 25 and 26 which support this is found in the last paragraph in each claim wherein they state "a contoured bolus overmolded". Paragraph [0021] of the Applicant's specification discloses that Fig. 8 is a different embodiment and is distinct in that the tip is produced through an overmolding process. Claims 27 and 28 are also directed to a different non-elected species, Species E (Fig. 13). The claim language in claim 27 which supports this is found in the second to last paragraph of claim 27 which states "the intermediate wall extends distally beyond the second opening" as well as in the last paragraph which discloses that a first projection is mounted on the first side of the extension portion, which clearly is directed towards Species E.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, and consequently depending claims 2-6 and 8-13, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the bolus" in line 15. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Quinn (US 2005/0182354). Quinn discloses a distal tip for a catheter (Figs. 19-31, for example) comprising: first and second lumens (Fig. 24, 122 and 120) extending therethrough, wherein in an operative configuration the first and second lumens are coupled to first and second lumens of a dual lumen catheter (110); a first opening (132) fluidly connected to the first lumen (122) for inflow of fluid from a body lumen into which

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the distal tip is inserted in a normal mode of operation and for outflow of fluid thereinto in a reverse mode of operation ([0015]-[0017]); a second opening (130) fluidly connected to the second lumen (120) being disposed distally from the first opening and separated therefrom by a selected stagger distance for outflow of fluid therefrom when the catheter is in the normal mode of operation and for inflow of fluid from the body lumen in a reverse mode of operation ([0015]-[0017]); a contoured flow deflection (most clearly labeled in Fig. 1 as 60) element directing, in the reverse mode of operation, outflow from the first opening away from the second opening ([0076] state that if the flow is reversed such that blood flows out through the first opening then the inflow of blood through the second opening does not mix with the outflow of blood because the two are staggered apart, and the flow of blood out from the first opening (132) would inherently hit the ramped portion of the bolus (60) and be deflected upward and away from the second opening); a contoured outlet portion (Fig. 21, 114) of the second opening reducing an outflow velocity therefrom in the normal mode of operation ([0023]); and side walls (Figs. 24 and 25, 136; [0070]) extending between the first opening (132) and the contoured flow deflection element (also shown in Figs. 15, 17, and 26-31).

In reference to claim 2, Quinn further discloses that the first and second openings are disposed on opposite sides of the distal tip (Fig. 21) with respect to a longitudinal axis thereof.

In reference to claim 3, Quinn further discloses that the first and second openings have orifices extending in planes angled with respect to a longitudinal axis of the distal tip (Fig. 15).

In reference to claim 4, Quinn further discloses that the contoured flow deflection element (114) is adapted to direct outflow from the second opening away from the first opening in the normal mode of operation ([023]).

In reference to claim 5, Quinn further discloses that the tip comprises an atraumatic tip formed at a distal end of the distal tip (Fig. 21, 114).

In reference to claim 6, Quinn further discloses that the first opening includes a first ramp portion (Fig. 10, portions labeled "R") deflecting outflow therefrom away from a longitudinal axis of the distal tip in the reverse mode of operation ([0024]).

In reference to claim 8, Quinn discloses that the second opening (130) includes a second ramp portion (Fig. 21) deflecting outflow from the second opening away from a longitudinal axis of the distal tip in the normal mode ([0023]).

In reference to claim 9, Quinn discloses that the second opening comprises an expanded section increasing an exit plane cross sectional area of the second orifice (Fig. 15, 150 discloses an embodiment in which the orifice's cross-sectional area is increased by an expanded section).

In reference to claim 10, Quinn discloses that the first and second lumens have substantially D shaped cross sections (Fig. 18).

In reference to claim 11, Quinn discloses a contoured bolus (Fig. 5, 14) including a first ramp substantially aligned with the first opening (near opening 32), a second

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ramp aligned with the second opening (near opening 30) and an atraumatic distal tip (42).

In reference to claim 12, Quinn discloses that the maximum radial dimension of the contoured bolus is less than a radius of a catheter to which the distal tip is to be coupled ([0018]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2005/0182354) in view of Dasse et al. (US Patent No. 5,171,216). Quinn discloses the device substantially as claimed, however, Quinn does not disclose expressly that the stagger distance between the openings is between 1 and 1.5 cm. Dasse, however, discloses a distal tip of a catheter with a stagger distance between the openings (Fig. 3, 14 and 16) that can be anywhere in the range of 1-4 cm (see col. 5, lines 7-13).

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Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn with the stagger distance as specified by Dasse in order to provide an optimal distance between the openings such that mixing of the blood does not occur, yet also to ensure that the distal tip of the catheter can still be maneuverable within a vascular system.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2005/0182354), herein after Quinn 2005, in view of Quinn (5,451,216), herein after Quinn '216. Quinn discloses a flow control tip for a multi-lumen catheter comprising: an attachment portion (Fig. 5, 34) adapted to fluidly connect to a distal portion of a catheter; and a contoured bolus (14) defining at least a portion of an inlet and outlet of the distal tip (near 32 and 30), and a flow deflector Fig. 1, 60) directing fluids exiting the inlet in a first mode away from the outlet ([0024]) and side walls (Figs. 24 and 25, 136; [0070]) extending between the inlet and the bolus, wherein the contoured bolus defines a specified stagger distance between the inlet and the outlet (Fig. 1).

Quinn 2005, however, does not disclose that the tip, when coupled to the catheter, the inlet is coupled to one of the lumens and the outlet is coupled to the other lumen. Quinn '216, however, discloses a flow control tip for a catheter (Fig. 4) which can be attached directly to a lumen (at 31 and 32) and the flow control tip has side walls (Figs. 5, 6 and 9; element 56). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn 2005 with the attachment to lumens, as taught by Quinn '216, in order to provide a more secure attachment to the catheter.

In reference to claim 17, Quinn 2005 discloses that the contoured bolus further comprises a second flow deflector (Fig. 5, 42) directing fluid exiting the outlet in a second mode away from the inlet.

In reference to claim 18, Quinn 2005 discloses that the inlet (32) and the outlet (30) are formed on opposite surfaces of the contoured bolus.

In reference to claim 19, Quinn 2005 discloses that the flow deflector comprises a ramp (Fig. 1, 60) disposed adjacent an inlet opening (32).

In reference to claim 20, Quinn 2005 discloses that the contoured bolus defines an expanded section (Fig. 15, 150) at the outlet increasing an exit plane cross-sectional area of the outlet.

In reference to claim 21, Quinn 2005 discloses that the size of the expanded section is selected to reduce an exit pressure of the fluid to a predetermined level ([0023]).

In reference to claim 23, Quinn 2005 discloses that the attachment portion is adapted for attachment to the catheter by thermal bonding ([0065]).

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-13, 16-21 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

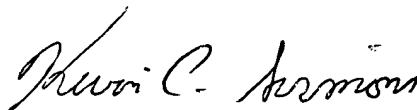
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in cursive script, reading "Kevin C. Sirmons", positioned below the printed name and title.